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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,491	01/11/2002	Chaim Sukenik	LUZZATTO 3.0-095	6432
530	7590	05/19/2004	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			VENIAMINOV, NIKITA R	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/043,491	<b>Applicant(s)</b> SUKENIK ET AL.	
	<b>Examiner</b> Nikita R Veniaminov	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on RCE filed on 04/19/2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 17-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-16 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/19/2004 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:  
  
A person shall be entitled to a patent unless –  
  
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
3. Claims 1, 2 and 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Sorensen et al. (US 6,500,108 B1). Sorensen et al. ('108) teach a device or temporary, or permanent therapeutic implant, or stent for use in angioplasty comprising a surface layer that has incorporated therein at least one

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radioactive nuclide (see Figure 2(18) and column 5, lines 19-21); a substrate and a self assembled layer that has incorporated therein at least one radioactive nuclide, and having no other protective layers or coating over said self-assembled layer (see Figure 2(16 and 18) and column 5, lines 19-21); wherein the self-assembled layer is an anchored SAM (see column 5, lines 16-30); wherein the anchored SAM is selected from the group consisting of monolayers anchored by thiol or amine (see column 6, lines 8-41); the device comprising a chemically functionalized SAM incorporating at least one radioactive nuclide such as I-131 (see column 16, lines 26-33) attached at the surface of the device (see column 9, lines 38-48).

4. Claims 1-4, 7-13, 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Weadock (US 6,264,596 B1). Weadock ('596) teaches a device, such as temporary or permanent implant (stent) for use in angioplasty, which comprises a substrate and at least one self-assembled, surface layer, which layer has incorporated therein at least one radioactive nuclide, wherein the substrate is selected from the group consisting of stainless steel, Nitinol and polymers (see column 3, lines 35-37 and column 4, lines 23-33); wherein the self-assembled layer is an anchored SAM (see column 3, lines 29-34); wherein the surface layer is formed of a radioactive material such as I-131 (see column 4, lines 23-33 and column 5, lines 25-37); wherein a chemically functionalized SAM incorporating radionuclides attached at the surface of the device (see column 4, lines 23-33 and column 5, lines 25-37); and wherein the surface layer is formed

of radioactive material that has been activated to induce radioactivity therein after its final formation (see column 5, lines 4-37).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (US 6,264,596 B1) as applied to claims 3 and 4 above, in view of Sorensen et al. (US 6,500,108 B1). Weadock ('596) teaches a device, which is a temporary or permanent implant (stent) as described in paragraph 4 above, but he does not teach an anchored SAM selected from the group consisting of monolayers or films anchored by siloxane, thiol, amine and phosphonate. However, Sorensen et al. ('108) teach a device or temporary, or permanent therapeutic implant, or stent comprising a self-assembled layer, which is an anchored SAM (see column 5, lines 16-30); wherein the anchored SAM is selected from the group consisting of monolayers anchored by thiol or amine (see column 6, lines 8-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the anchored SAM of Weadock ('596) with the anchored SAM of Sorensen et al. ('108) in order to create the strong bonds between the SAM and the attached radionuclides.

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7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (US 6,264,596 B1). Weadock ('596) teaches a device, which is a temporary or permanent implant (stent) as described in paragraph 4 above, but he does not teach a temporary or permanent implant comprising a radioactive self-assembled surface layer having a thickness of less than 10 nm. It would have been obvious to one of ordinary skill in the art at the time of the invention to determine through routine experimentation an appropriate thickness for implementing the radioactive self-assembled surface layer, including radioactive self-assembled surface layer with the thickness Applicant provides in the claim.

***Allowable Subject Matter***

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art, either alone or in combination, teaches or suggests a device wherein an anchored SAM is selected from the group consisting of monolayers or films anchored by phosphonate.

9. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

9. Applicant's arguments filed 04/19/2004 have been fully considered but they are not persuasive. Applicant's argues, see Applicant Arguments or Remarks Made in an Amendment, that "claims 1-16 are currently pending in the instant patent application". Applicant amended claims 3, 4, 6-9 and 14-16; claims 1, 2 and 10-13 were indicated as withdrawn from further consideration. In the Response to Restriction Requirement filed on 03/24/2003 Applicant elected claims 1-16, and claims 17-35 were withdrawn from further consideration. As such appears that Applicant meant to cancel claims 1, 2 and 10-13. Since Applicant did not cancel claims 1, 2 and 10-13 they were treated as pending. Examiner states that rejection of claims 1, 2 and 10-13 under 35 U.S.C. 102(e) over Sorensen et al. (US 6,500,108 B1) is deemed proper. Upon further consideration, a new ground(s) of rejection is made in view of Weadock (US 6,264,596 B1) and Sorensen et al. (US 6,500,108 B1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (703) 605-0210. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703) 308-3130.

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The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



May 06, 2004.

Nikita R Veniaminov  
Examiner  
Art Unit 3736

  
ROBERT L. NASSER  
PRIMARY EXAMINER